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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,838	02/12/2004	Mark K. Wedel	FMDL0001US	5903

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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

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10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,838	WEDEL ET AL.	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 7-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 7-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 18, 2007 has been entered.

Status of Claims

Claims 1-3 and 7-24 are currently pending and under examination on the merits.

Response to Arguments

Applicant's arguments with respect to claims 1-3 and 7-8 have been considered but are moot in view of the new ground(s) of rejection. See below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 9-16 are rejected under 35 U.S.C. 102(a) as being anticipated by PR Newswire (New York: February 11, 2003).

The claims are drawn to a method of treating pouchitis in a patient comprising administering a chemically modified antisense pharmaceutical composition comprising SEQ ID NO:1, wherein the pharmaceutical composition is known as ISIS 2302.

PR Newswire teaches a method of treating ulcerative colitis/pouchitis in a patient comprising administering ISIS 2302. The article reveals that the studies for the treatment of UC/pouchitis with ISIS 2302 are undergoing Phase II trials. See pages 4-6 of the 11-page printout. Accordingly, all limitations set forth in the claims are taught by PR Newswire.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 7-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over PR Newswire as applied to claims 1 and 9-16 above, and further in view of Bennett et al. (US 6,111,094).

The claims are drawn to a method of treating pouchitis in a patient comprising administering a pharmaceutical composition known as ISIS 2302, wherein the composition is formulated for rectal use.

PR Newswire teaches a method of treating ulcerative colitis/pouchitis in a patient comprising administering ISIS 2302. The article reveals that the studies for the treatment of UC/pouchitis with ISIS 2302 are undergoing Phase II trials. PR Newswire does not teach that the ISIS 2302 compound is formulated for rectal use.

Bennett et al. teach that pharmaceutical compositions comprising ICAM-1 modulating antisense oligonucleotides such as ISIS 2302 can be administered via a rectal mode by formulating the compositions in enemas or suppositories. They also teach that the ISIS 2302 pharmaceutical composition comprises a pharmaceutically acceptable carrier such as a penetration enhancer or it can be in a salt form. See columns 13-14 and 18-21. They teach that ISIS 2302 can be used in a method of treating various inflammatory disorders such as ulcerative colitis. See column 57.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of treating UC/pouchitis of PR Newswire by formulating the ISIS 2302 compound for rectal use in enemas or suppositories further comprising a penetration enhancer as taught by Bennett et al.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because Bennett et al. expressly taught that ISIS 2302 compound can be

designed for rectal administration in the form of enemas or suppositories or salt and that the compound can comprise a penetration enhancer for treatment of various inflammatory disorders such as ulcerative colitis. Since the method of treating ulcerative colitis is equivalent to or interchangeable with that of treating pouchitis as taught by PR Newswire, it would have been obvious to one of ordinary skill in the art to apply the ISIS 2302 compound formulated for rectal use, which was known to be suitable for treatment of ulcerative colitis by Bennett et al., to the method of treating pouchitis. Since the skills and method steps required to make and use the claimed invention were within the technical grasp of one of ordinary skill in the art, one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. Accordingly, the claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 7-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3 of U.S. Patent No. 6,169,079 B1 in view of PR Newswire (New York: February 11, 2003).

Both instant claims and reference claims are drawn to treating an inflammatory disease by administering an antisense pharmaceutical composition comprising ISIS 2302, which decreases the expression/activity of ICAM-1. The specification of 6,169,079 B1 teaches that the pharmaceutical composition "may be administered in a number of ways", which include rectal route of administration in the form of suppositories. See column 9, lines 11-20. Further, the specification of 6,169,079 B1 expressly states, "ISIS 2302...was the most active of the series". See column 19, lines 4-7. Further, the specification of 6,169,079 B1 teaches that the inhibition of ICAM-1 expression is "expected to have significant therapeutic benefits in the treatment of disease". See column 12, lines 30-33.

PR Newswire teaches a method of treating ulcerative colitis/pouchitis in a patient comprising administering ISIS 2302. The article reveals that the studies for the treatment of UC/pouchitis with ISIS 2302 are undergoing Phase II trials.

Although the reference claims do not recite treatment of pouchitis *per se,* it would have been obvious to one of ordinary skill in the art to use the methods in the reference claims to treat pouchitis with a reasonable expectation of success, because PR Newswire taught that ISIS 2302 was already undergoing Phase II trials for treatment of pouchitis/ulcerative colitis as of the earliest filing date sought in the instant application.

Claims 1-3 and 7-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-11, 16-17, and 19 of U.S. Patent No. 6,096,722 in view of PR Newswire (New York: February 11, 2003).

The reference claims are drawn to a method of treating an inflammatory disease comprising administering ISIS 2302 formulated in a penetration enhancer, wherein the inflammatory disease is ulcerative colitis. The specification of 6,096,722 teaches that the pharmaceutical composition "may be administered in a number of ways", which include rectal route of administration in the form of suppositories. See columns 17-18. Although the reference claims do not recite treatment of pouchitis *per se,* it would have been obvious to one of ordinary skill in the art to use the methods in the reference claims to treat pouchitis with a reasonable expectation of success, because PR Newswire taught that ISIS 2302 was already undergoing Phase II trials for treatment of pouchitis/ulcerative colitis as of the earliest filing date sought in the instant application.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner
Art Unit 1635